REMARKS

In response to the office action mailed October 9, 2008, Applicants have respectively replaced the phrases "a surface on the blood-contacting side" and "the reverse side of the surface on the blood-contacting side" recited in claims 1-3 with "an inner surface" and "an outer surface" to promote clarity. Support for this amendment can be found at, e.g., page 21, lines 1-5 and Table 1 of the specification. In addition, Applicants have removed the phrase "larger than" from "at least 1.1 times larger than" recited in claim 1. Support for this amendment can be found at, e.g., Table 1 of the specification and the abstract of International Application No. PCT/JP2004/07990, from which this application claims priority. Finally, Applicants have corrected the deficiencies in claims 1-4 and 9. Claims 1-9 are presented for examination.

Rejection under 35 U.S.C. §112, 2nd paragraph

Claims 1-4 and 9 are rejected as indefinite. Applicants have amended claims 1-4 and 9 to obviate this rejection and request that this rejection be withdrawn.

Rejection under 35 U.S.C. §101

Claim 9 is rejected on the ground that "the claimed recitation of a use, without setting forth any steps involving the process, resulting in an improper definition of a process." Applicants have amended claim 9 to obviate this rejection and request that this rejection be withdrawn.

Rejection under 35 U.S.C. §103(a)

Claims 1-8 are rejected as being obvious from Kawata et al., U.S. Patent No. 5,340,480 ("Kawata").

Independent claim 1 is discussed first. It recites a hollow fiber membrane that includes a polysulfone-based resin and a hydrophilic polymer (e.g., a polyvinylpyrrolidone). Claim 1 also recites that (A) the content of the hydrophilic polymer in the uppermost layer of an inner surface is at least 1.1 times the content of the hydrophilic polymer in the proximate layer of the inner surface, and (B) the content of the hydrophilic polymer in the uppermost layer of an outer

surface is at least 1.1 times the content of the hydrophilic polymer in the uppermost layer of the inner surface. In particular, feature (B) can result in membranes that have improved blood compatibility and priming capacity, and have reduced possibility of invasion of endotoxin in the dialyzate into the blood site. See, e.g., the specification, page 19, line 30 to page 20, line 31.

Kawata describes a polysulfone hollow fiber membrane having an inner skin layer containing a polysulfone and a polyvinylpyrrolidone. *See, e.g.*, the abstract. A content of the polyvinylpyrrolidone in the skin layer on the inner surface is higher than that in an outer surface layer. *Id.* In other words, Kawata teaches that the content of the polyvinylpyrrolidone in the outer surface layer is **lower than** that in the skin layer on the inner surface. Kawata does not disclose or render obvious a membrane in which the content of a hydrophilic polymer (e.g., a polyvinylpyrrolidone) in the uppermost layer of the outer surface is **at least 1.1 times** the content of the hydrophilic polymer in the uppermost layer of the inner surface, as recited in claim 1. Indeed, Kawata teaches that "a ratio of the weight percent vinylpyrrolidone-based polymer in said skin layer [on the inner surface] to the weight percent vinylpyrrolidone-based polymer in an outer surface layer of the membrane is at least 1.1." *See, e.g.*, claim 1; emphases added. Thus, Kawata **teaches** one skilled in the art **away** from claim 1, which recites that the content of a hydrophilic polymer (e.g., a polyvinylpyrrolidone) in the uppermost layer of the outer surface of a membrane is at least 1.1 times the content of the hydrophilic polymer in the uppermost layer of the inner surface. In short, Kawata teaches one skilled in the art away from feature (B) recited in claim 1.

Further, Kawata does not disclose or render obvious feature (A) recited in claim 1, i.e., the content of the hydrophilic polymer in the uppermost layer of an inner surface of the hollow fiber membranes is at least 1.1 times the content of the hydrophilic polymer in the proximate layer of said inner surface. Indeed, Kawata is entirely silent on a proximate layer of the inner surface, let alone a proximate layer of the inner surface that contains a hydrophilic polymer in a content at least 1.1 times that in the uppermost layer of the inner surface, as recited in claim 1.

For at least the reasons set forth above, claim 1 is not obvious from Kawata. As claims 2-9 depend from claim 1, they also are not obvious from Kawata.

Applicants submit that claim 3 is not obvious from Kawata on an additional, independent ground.

Specifically, claim 3 recites a membrane in which the content of a hydrophilic polymer (e.g., a polyvinylpyrrolidone) is 25 to 50 mass % at the uppermost layer of the outer surface. Such membranes can have improved blood compatibility and priming capacity, and reduce possibility of invasion of endotoxin in the dialyzate into the blood site. See, e.g., the specification, page 19, line 30 to page 20, line 31.

By contrast, Kawata discloses that its membrane contains from about 1.9 to 22.9 wt% of a polyvinylpyrrolidone in the outer surface. For example, Kawata teaches in Example 3 that "[t]he obtained hollow fiber membranes ... had a content ratio by weight of PVP [i.e., polyvinylpyrrolidone] to PS [i.e., polysulfone] of 32/68 in the skin layer on the inner surface and a ratio of the weight percent PVP in the skin layer on the inner surface to the weight percent PVP in the outer surface layer is 16.5." *See* column 16, lines 38-45. In other words, the weight percentage of PVP in the outer surface layer in this example is about 1.9 wt% (i.e., 32 wt% / 16.5 $\approx$ 1.9 wt%). As another example, Kawata teaches in Comparative Example 2 that "[t]he obtained hollow fiber membranes ... had a content ratio by weight of PVP to PS of 16/84 in the skin layer on the inner surface and a ratio of the weight percent PVP in the skin layer on the inner surface to the weight percent PVP in the outer surface layer is 0.7." *See* column 18, lines 34-40. In other words, the weight percentage of PVP in the outer surface layer in this example is about 22.9 wt% (i.e., 16 wt% / 0.7 $\approx$ 22.9 wt%). The weight percentages of PVP in the outer surface layer in the other examples described in Kawata all fall within the range from about 1.9 to 22.9 wt%. Kawata does not disclose or render obvious a membrane in which the content of a hydrophilic polymer is 25 to 50 mass % at the uppermost layer of the outer surface, as recited in claim 3. Indeed, given that Kawata discloses a membrane in which the content of a hydrophilic polymer is no more than about 22.9 wt% in the outer surface layer, it **teaches** one skilled in the art **away** from the membrane of claim 3, which includes a hydrophilic polymer at least 25 mass % at the uppermost layer of the outer surface.

Thus, for at least the reasons set forth above, claim 3 also is not obvious from Kawata on this additional, independent ground.

CONCLUSION

Applicants submit that the grounds for rejection asserted by the Examiner have been overcome and that all pending claims are now in condition for allowance, which action is requested.

Any circumstance in which Applicants have: (a) addressed certain comments of the Examiner does not mean that Applicants concede other comments of the Examiner; (b) made arguments for the patentability of some claims does not mean that there are not other good reasons for the patentability of those claims and other claims; or (c) amended or canceled a claim does not mean that Applicants concede any of the Examiner's positions with respect to that claim or other claims.

Please apply any charges to deposit account 06-1050, referencing Attorney's Docket No. 19461-0002US1.

Respectfully submitted,

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